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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,770	08/19/2003	Surekha Palreddy	279.579US1	4115

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EXAMINER

SCHAETZLE, KENNEDY

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 06/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/643,770	PALREDDY ET AL.	
	Examiner	Art Unit	
	Kennedy Schaetzle	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-10,20,24 and 25 is/are rejected.
- 7) ☒ Claim(s) 3,11-19 and 21-23 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 August 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the computation of a noise statistic (see claim 1), the calculation of a noise floor (claim 3, etc.), etc., must be shown in Fig. 2 (or in new figures incorporating the various steps set forth in the method) or the feature(s) canceled from the claim(s). Likewise, the various means set forth in claim 24 must be shown or the feature(s) canceled from the claim(s) (stating that the microprocessor of Fig. 1 is a showing of all the means will be considered inadequate since the material in the very least admits of more detailed illustration). No new matter should be entered.

Corrected drawing sheets are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 2, 4-10, 20, 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al. (Pat. No. 6,029,086) in view of Adams et al. (Pat. No. 4,589,420).

Regarding claim 1 (with a similar line of reasoning applying to apparatus claim 24), Kim et al. disclose a method for operating a cardiac rhythm management device comprising: sampling an electrogram signal from a sensing channel of the device to obtain a series of samples (see element 26), where each sample can be designated by $X(n)$ with n an integer; determining whether each sample represents a local peak or not (note element 42 and the associated text), computing a local peak density in a predetermined number of consecutive samples (note col. 3, lines 4-8); computing a noise flag (note the present specification page 7, par. 2) as either set or cleared in accordance with the computed local peak density (the examiner considers the device of Kim et al. to set or clear a noise flag by virtue of the fact that a true or false condition must be computed as a result of the logic operation 102 in Fig. 5, and that such a condition is most typically the result of an asserted or not asserted logic gate/comparator output), wherein the noise flag is set if the local peak density exceeds a first threshold value (such as when the peak density exceeds 500 bpm as shown in decision diamond 102); and, estimating a noise level in the electrogram signal by computing a noise statistic from a series of samples when the noise flag is set (note col. 9, lines 11-15, as well as the present specification page 8, lines 1-5).

While Kim et al. do not explicitly discuss a local peak detecting algorithm such as set forth in lines 4-9 of claim 1, once the idea of sensing local peaks has been established by Kim et al., those of ordinary skill in the art would have seen the obviousness of employing any of the many known viable techniques to detect such peaks. Adams et al., disclose a related system for processing cardiac signals wherein local peaks are ascertained by searching for changes in slope sign (see the text

abridging cols. 6 and 7 for a discussion of local peak detection). The applicants' recitation of local peak detection is simply another way of saying that one is detecting a change in slope sign about a sample point. For example, the requirement that the amplitude of sample $X(n)$ be "...either: 1) greater than the amplitude of the preceding sample $X(n-1)$ and also greater than the amplitude of the subsequent sample $X(n+1)$ or 2) less than the amplitude of the preceding sample $X(n-1)$ and also less than the amplitude of the subsequent sample $X(n+1)$," for it to constitute a peak, is the same as saying the value of $X(n)-X(n-1)$ (i.e., the slope or rise of the segment prior to the sampling point $X(n)$) must be a positive value, as well as the slope of the subsequent segment $X(n)-X(n+1)$ (or as Adams et al. define slope, $X(n+1)-X(n)$ must be a negative number). Likewise for the detection of a local minimum where $X(n)$ must be smaller in amplitude than sample points on either side of it.

Regarding the use of threshold values, this limitation can easily be met since all amplifiers, A/D devices, etc., inherently have a limit to their sensitivity. Any signal change falling below this threshold of sensitivity will not be detected and therefore will not be counted as a local peak.

In summary, the applicants give no criticality to the exact method used to detect local peaks, and the prior art methods appear to work equally as well. Any detection method capable of providing a measure of peak density within a sample period would have been acceptable to those of ordinary skill in the art. A detected peak is a detected peak regardless of the manner in which it was detected.

Regarding claim 2, note the 180 bpm threshold set forth in decision diamond 102 of Fig. 5.

Concerning claim 4, the particular statistic used to calculate the measure of noise present in the system would have been considered a matter of obvious design by those of ordinary skill in the art. The applicants give no criticality to the use of any one statistical calculation over the other. Furthermore, given that Kim et al. suggest one may use the maximum amplitude of noise or the average of all noise deflections, those of ordinary skill would have readily recognized the calculation of the absolute peak to be

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substantially similar to the determination of the maximum amplitude, and the average calculation to relate to the calculation of a median or mean value.

Regarding claims 5-7, by taking an average of the amplitudes of the detected and counted peaks, one is inherently using the same samples used to determine peak density. Peak density is determined during a predetermined window NMW.

Regarding claims 8-10, note col. 3, lines 24-34.

Regarding claims 20 and 25, see the abstract and related text in the detailed description of the patent.

Allowable Subject Matter

4. Claims 3, 11-19 and 21-23 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Regarding claim 3, the prior art does not appear to disclose calculating a noise floor when a noise flag is cleared, but rather when a noise flag is set.

Concerning claim 11, there does not appear to be a teaching in the prior art of record for modifying the Kim et al. reference to include an estimate of a noise floor by calculating a noise statistic from a series of samples when the noise flag is cleared.

Regarding claim 14 and claims with related limitations, the prior art of record does not appear to disclose statistical analysis over a series of sample windows, with no teachings to modify the Kim et al. reference available.

Conclusion

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy Schaetzle whose telephone number is 703 308-2211. The examiner can normally be reached on 9:30 -6:00.

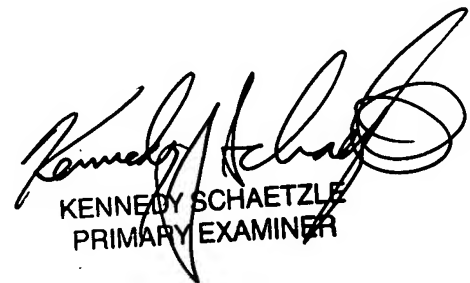
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703 308-0851. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KJS

June 20, 2004



KENNEDY SCHAEETZLE
PRIMARY EXAMINER